STATE OF VERMONT GREEN MOUNTAIN CARE BOARD

In re: Rutland Regional Medical Center,)	
Replacement of Nuclear Medicine Camera)	Docket No. GMCB-012-16con
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)	

STATEMENT OF DECISION AND CERTIFICATE OF NEED

Introduction

Rutland Regional Medical Center (RRMC, the hospital, or the applicant) requests a certificate of need (CON) to replace its nuclear medicine camera at a cost of \$2,840,596. For the reasons outlined below and subject to the conditions contained herein, we approve the application.

Jurisdiction

The Board has jurisdiction over the certificate of need process pursuant to 18 V.S.A. § 9375(b)(8). The proposed project, a health care facility as defined in 18 V.S.A. § 9432(8), is subject to certificate of need review because the cost of the replacement medical equipment exceeds \$1 million. 18 V.S.A. § 9434(b)(2).

Procedural History

On June 29, 2016, RRMC filed a Letter of Intent with the Board to replace its nuclear medicine camera. RRMC filed a certificate of need application on May 7, 2017. The Board published notice of the application on its website on May 26, 2017, and receiving no requests for intervention, the application was reviewed by the Board on an expedited basis. After requesting and receiving additional information from the applicant, the Board closed the application on June 27, 2017.

Findings of Fact

- 1. The applicant seeks to replace its Infinia Hawkeye nuclear medicine camera with a new Discovery NM/CT 670 Pro nuclear medicine imaging system at a cost of \$2,840,596. The existing equipment is twelve years old and fully depreciated. Application (App.) at 2, 5.
- 2. The applicant does not plan to relocate the nuclear medicine suite but will renovate 1,391 square feet (sq. ft.) of existing space and add 779 sq. ft. of new construction. The newly renovated area and additional space is needed to accommodate the new, larger camera, properly position the control room relative to the new camera, provide sufficient space for support areas and create efficient work flow, and relocate the Hot Lab within the nuclear medicine suite. App. at 3.

- 3. The nuclear medicine camera is standard technology found in most hospitals and is a core imaging modality used by cardiologists, primary care physicians, physician specialists, emergency department physicians and hospitalists. The equipment is primarily used for cardiac imaging and general nuclear medicine imaging, and is used in RRMC's cancer center for diagnostic imaging including tumor localization, bone and lymph node localization scans. Nuclear medicine is also vital for patients entering the Emergency Department with chest pain, pulmonary emboli and GI bleeds. App. at 2.
- 4. The Discovery NM/CT 670 Pro is faster than the equipment it replaces, reducing scan time and patient exposure to radiation. The applicant estimates that ten percent of patients requiring scans could see a reduction in radiopharmaceutical costs due lower dosage use. App. at 6. In addition, the shorter scan time allows patients to more easily remain still during the scan, which increases the quality of the image and patient comfort. App. at 2.
- 5. The Nuclear Regulatory Commission requires tracking of all radiopharmaceutical doses, by patient, in the Nuclear Medicine Information System. The tracking and protocols utilized include staff review of patient information to reduce the risk of repetitive testing. Prior to carrying out each exam, the Nuclear Medicine Department must validate that the patient has not received a recent prior exam. App. at 5.
- 6. The location of RRMC's nuclear medicine camera remains the same, conveniently located near the emergency department and other related departments. The proposed renovations and construction are compliant with applicable FGI guidelines. App. at 3-4.
- 7. As confirmed in writing, the applicant is working with Efficiency Vermont to ensure that the project implements reasonable energy conservation measures in the areas of heating, ventilation, air conditioning and lighting. App. at 4; Letter from Efficiency Vermont (April 9, 2017).
- 8. The applicant does not project that use of the new equipment will increase utilization and no new services are associated with the replacement equipment. App. at 2.
- 9. In its FY 2016 hospital budget submission to the Board, RRMC included the project as a non-CON project costing \$950,000. In its FY 2017 budget, however, the project appeared as a \$2.2 million cost, based on the applicant's decision to renovate and reconfigure space more efficiently, and to construct additional space to accommodate the larger footprint of the new equipment and associated spaces. App. at 5.
- 10. The total project cost is \$2,840,596. App. at Table 1. The project will be paid for with an equity contribution. App. at Table 2, *Debt Financing Arrangement*. RRMC's rates will not be impacted by the project. App. at 6. The existing equipment is fully depreciated. App. at 5.

Conclusions of Law

Vermont law outlines eight statutory criteria that an applicant must meet before a CON will issue. The applicant bears the burden to demonstrate that it has met the criteria. GMCB Rule 4.000, § 4.302.3.

Under the first criterion, the applicant must show that the application is consistent with the Health Resource Allocation Plan (HRAP). The HRAP, last updated in 2009, identifies needs in Vermont's health care system, resources to address those needs, and priorities for addressing them on a statewide basis. 18 V.S.A. § 9437(1). We find that the applicant has demonstrated that this project is consistent with the relevant HRAP standards. *See*, *e.g.*, HRAP Standard (Standard) 1.3 (collaborative approach has been taken or is not feasible); Standard 1.4 (volume of services is positively correlated to better quality, applicant can maintain appropriate volume, and project will not erode volume at any other Vermont facility); Standards 1.9, 1.10, 1.11,1.12 (project is cost-effective, energy efficient and conforms with applicable FGI Guidelines); Standard 3.4 (project has been included in hospital budget submissions); Standard 3.7 (existing equipment is fully depreciated); Standard 3.20 (addresses appropriateness of equipment distribution, availability of trained personnel and appropriate protocol to reduce repetitive testing); Standard 3.22 (evidence of clinical efficacy for diagnoses performed with equipment); Standard 3.23 (the equipment is needed, reduces costs and/or improves quality); Standard 3.24 (no conflicts of interest between the hospital, physicians and equipment purchase.)

We next conclude that the applicant has satisfied the second criterion, relating to the costs of the project. 18 V.S.A. § 9437(2) (project cost must be reasonable, sustainable by the applicant, project cannot cause undue increase in costs of care, and there are no less expensive alternatives). This project involves the replacement of a core piece of imaging equipment used in hospitals for cardiac imaging and general nuclear medicine exams. Nuclear medicine imaging is a standard modality used by cardiologists, primary care physicians, physician specialists, emergency department physicians and Hospitalists. Finding of Facts (Findings) ¶ 3,10. The applicant will fund the purchase and related construction and renovations with an equity contribution. Finding ¶ 10. The project will not increase the rates or cost of care, and an estimated ten percent of patients may see a reduction in cost. The applicant will not offer new services and expects no increase in volumes. Findings ¶¶ 8,9,10. There is also no less expensive alternative. The existing equipment is at the end of its useful life—it is twelve years old, and fully depreciated— and exposes patients to more radiation relative to the replacement equipment. Findings ¶¶ 2,3,4.

The third criterion requires the applicant to demonstrate an "identifiable, existing, or reasonably anticipated need" for the project. 18 V.S.A. § 9437(3). Nuclear medicine cameras are considered standard hospital equipment for physicians to effectively diagnose and treat patients with cardiac conditions, cancers and other conditions requiring general nuclear medicine exams. Nuclear medicine is also vital for patients entering the Emergency Department with chest pain, pulmonary emboli and GI bleeds. Findings ¶¶ 2,3,4. We conclude that the applicant has demonstrated that the project is needed and therefore has satisfied this criterion.

Under the fourth criterion, the project must either improve the quality of health care, provide greater access for Vermonters, or both. 18 V.S.A. § 9437(4). The applicant has shown that the project improves health care quality; the new equipment will replace less-technologically advanced equipment, and by reducing scan time, will lessen the time a patient must remain motionless and exposed to harmful radiation. Findings ¶¶ 4,5. In addition, the shortened scan time will increase patient comfort and experience. Findings ¶¶ 3,4,5. The applicant has met this criterion.

The project will not have an undue adverse impact on other services provided by the applicant, satisfying the fifth criterion. *See* 18 V.S.A. § 9437(5). The applicant currently provides services using this equipment modality.

The sixth statutory criterion, that the project serves the public good, has been met for all the reasons discussed throughout this decision. 18 V.S.A. § 9437(6). The seventh criterion is not applicable as the there is no change in the service location which remains within the hospital. 18 V.S.A. § 9437(7) (applicant must consider availability of transportation services).

The final criterion relates specifically to new health care technology projects, and to the extent it is relevant, we conclude it has been satisfied.

Based on the above, we issue a certificate of need to the applicant, subject to the conditions outlined below.

CERTIFICATE OF NEED

Conditions:

- 1. The Certificate of Need shall be subject to the following terms and conditions:
 - A. The applicant shall comply with the scope of the project as described in the application and other materials it has submitted to the Board relevant to this project. This Certificate of Need is limited to the project and activities described therein.
 - B. The project as described in the application shall be fully implemented within three years of the date of this Certificate of Need or the Certificate of Need shall become invalid and deemed revoked.
 - C. Noncompliance with any provision of this Certificate of Need or applicable ordinances, rules, laws and regulations shall constitute a violation of this Certificate of Need and may be cause for enforcement action pursuant to 18 V.S.A. §§ 9445, 9374(i), and any other applicable law.
 - D. This Certificate of Need is not transferable or assignable and is issued only for the premises and entity named in the application.
 - E. If the applicant contemplates or becomes aware of a potential or actual nonmaterial change, as defined in 18 V.S.A. § 9432(12), or a material change as defined in 18 V.S.A.

- § 9432(11), to the scope or cost of the project described in its application and as designated in this Certificate of Need, it shall file a notice of such change immediately with the Board. The Board shall review the proposed change and advise the applicant whether the proposed change is subject to review.
- F. The applicant shall file implementation reports with the Board at six-month intervals starting from the date of this CON through the time the project is fully operational and all invoices have been paid. Implementation reports shall include information and analysis demonstrating that the project is in conformance with its scope as described in the application, and must identify any changes to the financing of the project. Provide a separate spreadsheet including the following columns: CON approved amount, expenditure for previous six-month period, expenditures for current six-month reporting period and reporting dates, dollars expended to date, dollars that remain, and percent over/under budget for each of the line items shown on Table 1 in the application.
- G. The Board may, after notice and an opportunity for the applicant to be heard, make such further orders as are necessary or desirable to accomplish the purposes of this Certificate of Need, and to ensure compliance with the terms and conditions of this Certificate of Need.
- H. All reports, notices, forms, information or submissions of any kind required to be submitted to the Board as a condition of this Certificate of Need shall be signed by the Applicant and verified by the chief executive officer, or by his or her designated representative.
- I. The conditions and requirements contained in this Certificate of Need shall remain in effect for the duration of the reporting period defined in paragraph F, above.

SO ORDERED.

Dated: July 26, 2017 at Montpelier, Vermont

s/ Cornelius Hogan)	
)	
s/ Jessica Holmes)	GREEN MOUNTAIN
)	CARE BOARD
s/ Robin Lunge		OF VERMONT
•)	
s/ Kevin Mullin		
)	
s/ Maureen Usurer)	

Filed: July 26, 2017